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STARA (Studies on Toxicity Applicable to Risk Assessment) Toxicity Data Base

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16. ABSTRACT

The Environmental Criteria and Assessment Office of the U.S. Environmental Protection Agency (EPA) has developed a toxicity data base to aid in the development of risk assessment methodologies and the assessment of health hazards from hazardous waste sites and chemical spills. The data base currently contains detailed animal toxicity data on nearly 200 chemicals and epidemiologic data on 30 chemicals. All relevant publications and original research articles describing the toxicity of a specific chemical were examined. Useful dose-effect data were extracted and encoded, and entered into EPA's IBM computer. Graphic summaries are generated by plotting exposure level vs. exposure duration. Statistical models to calculate human equivalent dose and duration have been programmed into the data base so that data on several species can be displayed on a single graph.

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ENVIRONMENTAL RESEARCH BRIEF

The STARA Toxicity Data Base

C. B. Farren[1] and R. C. Hertzberg[2]

Purpose

A toxic chemicals data base has been created by the U.S. Environmental Protection Agency's (EPAs) Environmental Criteria and Assessment Office-Cincinnati (ECAO-Cin) to aid in the development of risk assessment methodology and to facilitate the evaluation of potential public health dangers due to uncontrolled hazardous waste site releases and chemical spills. This data base, "Studies on Toxicity Applicable to Risk Assessment" (STARA), focuses on toxicity studies containing quantitative as well as descriptive information on a test animal or human study group, exposure and type of effects. For each chemical in the data base a toxicity summary table can be generated. A discussion of the STARA data base is presented featuring the types of information available, methods for revision and expansion, and future uses of the system.

Background

The design and implementation of ECAO's data base has been an ongoing program since the summer of 1982. Initially organized as a short-term research project to assist the implementation of the Comprehensive Environmental Response, Compensation and Liability Act of 1980 (Superfund), the impetus was to: (1) investigate toxic responses to certain chemicals in animals and humans; and (2) assemble such data in a methodical fashion so as to be easily accessed should emergency contaminations arise. Experimental studies cited in the data base are drawn from searches of peer-reviewed scientific publications similar to the searches conducted for the Ambient Water Quality Criteria Documents, Health Assessment and Drinking Water Documents, Reportable Quantities (RQs) and Health and Environmental Effects Profiles (HEEPs). Currently, the STARA data base contains animal toxicity data on nearly 200 chemicals and detailed epidemiologic data on 30 chemicals. These chemicals are listed at the end of this brief.

Requests for situation-specific assessments or other technical assistance occur irregularly and often involve repetitive retrieval of toxicity information on a variety of chemicals. The traditional procedure has been to manually extract and compile the desired data from various "hard copy" sources (research articles, review documents) on a case-by-case basis as the need arose. This approach was deemed outdated and inappropriate on the basis of economy, efficiency and even accuracy. The logical solution was to compile this bulk of information into some form of computer accessible data base.

After thoroughly investigating the existing data base management systems, it was concluded that no one specific system could satisfy the particular requirements unique to the Superfund mandate under which ECAO-Cin then operated. Work was initiated to develop a format which would be structured to allow for reproducibility and access by varied users, yet flexible enough for expansion and integration with other data processing systems.

Transposing the large, diverse documents and research articles used by the EPA into an effective and uniform source of information without sacrificing the integrity of the original material was a major task. Toxicity studies typically report a large number of variables, many of which are imprecisely defined or subject to considerable scientific interpretation. To ensure the best possible evaluations of such data for risk assessments, as much information as possible must be retained in the computer files. The data

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Chemical Data. Toxicity Tables in the STARA Data Base

Acenaphthene
Acetone
Acetonitrile
Acrolien
Acrylamide
Acrylonitrile
Aldicarb
Aldrin
Allyl alcohol
Aluminum
Ammonia
Antimony
Arsenic
Asbestos
Barium
Benzo(a)pyrene
Benzene
1,2-Benzenedicarboxylic acid, dibutyl ester
1,2-Benzenedicarboxylic acid, diethyl ester
Benzidine
Beryllium
Bis(2-chloroisopropyl)ether
Bis(2-chloroethyl)ether
Bis(chloromethyl)ether
Bismuth
Boron
Bromodichloromethane
Bromomethane
1,3-Butadiene
Cadmium
Captan
Carbon disulfide
Carbon tetrachloride
Chlordane
Chlorinated naphthalene
Chlorine
2-Chloro-1,3 butadiene
Chlorobenzene
Chlorodibromomethane
2-Chloroethyl vinyl ether
Chloroform
Chloromethane
Chloromethyl methyl ether
Chloronitrobenzene
Chlorophenol (m-, p-)
p-Chlorophenol
2-Chlorophenol
Chloropropenes
Chlorotoluenes
Chromium
Chrysene
Copper
Cresols
Creosote
Cyanides
Cyclohexanone
Cyclopentadiene
DDT
Demeton
Dibenzofurans
Dibromochloropropane
1,2-Dibromoetha[illegible]
Dichlorobenzene
Dichlorobenzidine
Dichlorobutenes
Dichlorodifluoromethane
1,1-Dichloroethane
1,2-Dichloroethane
Dichloroethylenes
Dichloromethane
2,4-Dichlorophenol
2,4-Dichlorophenoxyacetic acid
Dichloropropane
Dichloropropane/Dichloropropene
Dieldrin
Diethylamine
Dimethylamine
2,4-Dimethylphenol
1,3-Dinitrobenzene
4,6-Dinitro-o-cresol
2,4-Dinitrophenol
2,4-Dinitrotoluene
2,6-Dinitrotoluene
Dioxin (TCDD)
Diphenylhydrazine
Endosulfan
Endrin
Epichlorohydrin
Ethylbenzene
Ethylene oxide
Fluoranthene
Fluorides
Formaldehyde
Guthion
Haloethers
Heptachlor
Hexachlorobenzene
Hexachlorobutadiene
Hexachlorocyclohexane
Hexachlorocyclopentadiene
Hexachloroethane
Hexachlorophene
Isophorone
Isoprene
Kepone
Lanthanide Metals
Lead
Malathion
Manganese
Mercury
Methacrylonitrile
Methanol
Methoxychlor
Methyl ethyl ketone
Methyl isobutyl ketone
Methyl methacrylate
Methyl parathion
Mirex
Monochlorobutanes
n-Propyl alcohol
Naphthalene
Nickel
Nitrites/Nitrates
Nitrobenzene
Parathion
Polybrominated biphenyls
Polychlorinated biphenyls
Penta, hexachlorodibenzo-p-dioxin
Pentachlorobenzene
Pentachloronitrobenzene
Pentachlorophenol
Phenol
Phosphorus
Phthalate esters
Polynuclear aromatic hydrocarbons
Pyridine
Selenium
Silver
Tetrachlorobenzene
1,1,1,2-Tetrachloroethane
1,1,2,2-Tetrachloroethane
Tetrachloroethylene
2,3,4,6-Tetrachlorophenol
Tetraethyl lead (Plumbane)
Thallium
Toluene
Toxaphene
1,3-Transdichloropropene
Tribromomethane
Trichlorfon
2,4,6-Trichloroanaline
Trichlorobenzenes
1,1,1-Trichloroethane
1,1,2-Trichloroethane
Trichloroethene (Trichloroethylene)
Trichlorofluoromethane
2,4,5-Trichlorophenol
2,4,5-Trichlorophenoxy acetic acid
Trichloropropanes
Trinitrobenzenes
Uranyl nitrate
Vanadium(v)oxide
Vanadyl sulfate
Vinyl chloride
4-Vinyl-1-cyclohexene
Xylene
Zinc

structure that was selected includes not only all the measured information (body weight, daily dose, etc.), but also space for qualitative descriptions of the study.

Equally important was the need to provide data that was quickly accessible, either in whole (all information available) or in part (selecting for a certain route or duration of exposure, species type, etc.). ECAO-Cin has found this last capability highly beneficial when responding to waste site assessment questions, e.g., selecting only ingestion studies for use in assessing groundwater contamination.

Other data bases such as TOXLINE and TDB are structured for more efficient search strategies, but these are primarily literature citations with a brief text summarizing the article. STARA's uniqueness lies in its inclusion of all the available toxicity data in a format which allows complete statistical analysis, modeling and graphical presentations.

Database Development

The procedure for a toxicity table begins with the review and evaluation of all relevant publications including governmental, industrial and academic documents and original research articles describing the toxicity of the specific chemical. All useful dose-effect data are extracted and encoded into tables according to set guidelines (Tables 1, 2, and 3). The data from these source tables are then entered into files on the EPA's IBM computer system.

The time required to write and verify a toxicity table may range from two weeks to several months, depending mostly on the availability of original journal articles. Actual labor time spent is less, usually aroung 7-10 working days per toxicity table. The estimated cost to develop each chemical table and related graph, including labor and literature searches, is ~$500.00-$1000.00.

Graphic summaries of each toxicity table are generated by plotting exposure levels vs. exposure duration and using a symbol to represent the severity of the effect (Figure 1). Statistical models to calculate human equivalent dose and duration have been programmed into STARA so that data on several species can be displayed on a single graph. In Figure 1, for example, the equitoxic dose measure is mg per kg body weight, and the equitoxic duration measure is fraction of lifespan. Options in the plotting program allow the user to display all data or to select a specific area of interest (e.g., inhalation data, all acute oral data, etc.). These graphs are being used in ECAO-Cin's Rapid Response toxicity assessments and in evaluating various toxic equivalence models.

Table 1. Abbreviations for Toxocity Table Categories.

Categories

OBS	=	Observation or record number
CONT	=	Continuation item, part of the previous record
ROUTE	=	Exposure route, or primary route if sequential or simultaneous multiroute exposure
SPECIES	=	Species of test animal
NANIMALS	=	Number of animals in dose group
BODWGHT	=	Body weight (kg), estimated average weight over course of exposure period
EXPLEVEL	=	Exposure level in units reported by author
EXPDUR	=	Exposure duration
EXPSCH	=	Exposure schedule
STUDY	=	Purpose of study, main effect observed or sought in the study
ORGAN	=	Target organs
SEVERITY	=	Subjective category of effect severity based on EPA definitions in Table 3
REFERENCE	=	First author reference
YEAR	=	Year of reference
COMMENTS	=	Comments

Options for Each Category

ROUTE:
D = Dermal, F = Diet, G = Gavage, I = Inhalation, T = Intratracheal, O = Oral (not further specified), W = Water ingestion, P = Intraperitoneal, V = Intravenous, C = Subcutaneous, N = Not mentioned.

Options for Each Category (cont'd)

SPECIES:
CT = Cat, DG = Dog, GP = Guinea pig, HA = Hamster, HU = Human, MD = Monkey, MS = Mouse, PI = Pig, PR = Primate (unspecified), RB = Rabbit, RT = Rat, N = Not mentioned.

EXPOSURE DURATION:
DY = Day, HR = Hour, LF = Lifetime, MI = Minutes, MO = Month, WK = Week, YR = Year.

EXPOSURE SCHEDULE:
EX = Exposures, HD = Hr/Dy, DW = Day/Week, N = Not mentioned.

STUDY:
TX = Toxicity, IR = Irritation, CA = Cancer, RP = Reproductive alteration, CATX = Cancer/toxicity.

TARGET ORGAN:
BL = Blood, BN = Bone, BR = Brain, GI = Gastrointestinal, GR = Growth/wt. gain, HT = Heart, KD = Kidney, LV = Liver, LG = Lung, MT = Metabolism, MC = Muscle, N = Not mentioned, NL = Nasal passage, NS = Nervous system including CNS, CV = Nonspecific cardiovascular, OT = Other organs described in comments, RP = Reproductive system, SK = Skin, ---- = No effects were noted.

SEVERITY:
CTRL = Control group; NOEL = No-observed-effect level; NOAEL = No-observed-adverse-effect level; EL = Effect level, not necessarily adverse; AEL = Adverse-effect level; NOFEL = No-observed-frank-effect level; FEL = Frank-effect level; NOCEL = No-observed-cancer-effect level; CEL = Cancer-effect level; N = Not enough information.

Table 2. Sample Toxicity Table from the STARA Data Base

1,1,2,2-Tetrachloroethane
CAS NO.: 79-34-5 MOL. WT.: 167.84

OBS	CONT	ROUTE	SPECIES	NANIMALS	BODWGHT	EXPLEVEL	EXPDUR	EXPSCH	STUDY	ORGAN	SEVERITY	REFERENCE
1	2	I	RT	N		8200PPM	2DY	4.2HR/DY	TX	LVNSOT	FEL	HORIGUCHI
2	2											
3		I	MK	N		2000PPM	190DY	2HR/DY	TX	LV	AEL	HORIGUCHI
4		I	RT	6		1000PPM	4HR	1EX	TX	N	FEL	SMYTH
5		I	MS	6		600PPM	3HR	1EX	TX	MT	EL	TOMOKUNI
6	2											
7		I	RB	N		0.3PPM	9MO	4HD/7DW	TX	----	NOEL	NAVROTSKIY
8		I	RB	N		1.5PPM	9MO	4HD/7DW	TX	BLLVKD	EL	NAVROTSKIY
9	2											
10		I	RB	N		14.6PPM	9MO	4HD/7DW	TX	BLLVKD	AEL	NAVROTSKIY
11		I	RT	52		0PPM	265DY	4HD/7DW	TX	----	CTRL	SCHMIDT
12		I	RT	52		1.94PPM	265DY	4HD/7DW	TX	BLLVGR	AEL	SCHMIDT
13		I	MK	1	7.0	1975PPM	9MO	2HD/6DW	TX	BLLV	AEL	HORIGUCHI
14	2											
15		0	DG	1		1ML	365DY	150EX	TX	LVGI	AEL	BOLLMAN
16		I	HU	380		82PPM	1YR		TX	NSGI	AEL	LOBO-MENDONCA
17	2											
18	3											
19		I	HU	N		124PPM	N	N	TX	LV	AEL	JENEY
20		0	RB	7	2.5	0.5G/KG	1DY	1EX	TX	LVMT	EL	TRUHAUT

OBS	YEAR	COMMENTS
1	1962	EXP LVL=5900 OR 11400PPM, EXP DUR=3-6 HR;
2		LV=FATTY DEGENERATION, DEATH, NS=ANESTHESIA, OT=TISSUE CONGESTION;
3	1962	EXP LVL=1000 OR 4000PPM; MARKED VACUOLIZATION;
4	1969	DEATH OF 3 OF 6 ANIMALS IN 14DY;
5	1969	INCR. IN HEPATIC TRIGLYCERIDES, TOTAL LIPIDS;
6		DECREASE IN HEPATIC ENERGY STORES;
7	1971	EXP. DUR=TWA; RAT EXPOSED WITH SIMILAR RESULTS;
8	1971	SUPPRESSION OF HEMAGGLUTININ PRODUCTION;
9		PHASIC FLUCTUATIONS IN CHOLINESTERASE ACTIVITY;
10	1971	SAME AS ABOVE PLUS LV,KD DEGENERATION;
11	1972	UNSPECIFIED STRAIN AND SEX;
12	1972	INCR. BODY WT. INCR. WBC COUNT AND FAT IN LV;
13	1962	CYNOMOLGUS STRAIN;EXP LV=TWA;
14		VACUOLIZATION OF CYTOPLASM IN LV;
15	1931	ASSUMED EXP. ROUTE. EFFECTS- -JAUNDICE, DIARRHEA, INTEST. HEMORRHAGE;
16	1963	SURVEY; OCC. EXP; EXP. LEVEL: 65-98PPM AVG. TREMORS, GI PAIN,
17		SOFT SYMPTOMS IN 35%; APPEAR AFTER 3MO EXP; CONSISTENT SYMPTOMS AFTER 6MO EXP;
18		ALSO WORKERS DERMALLY EXPOSED TO UNKNOWN AMOUNTS; EXP. DUR=TEMPORARY, 1YR OR LESS;
19	1957	EPI. STUDY, OCC. EXP; EXP. LEVEL=1.5-247PPM; LV DYSFUNCTION;
20	1973	ACTIVITY OF ENZYMES (SGPT, SGOT, LDH) INDICATING HEPATOTOXICITY.

Table 2. (Continued)

OBS	CONT	ROUTE	SPECIES	NANIMALS	BODWGHT	EXPLEVEL	EXPDUR	EXPSCH	STUDY	ORGAN	SEVERITY	REFERENCE
21	2											
22		I	RT	N		1.94PPM	265DY	4HR/DY	TX	LVBL	AEL	DEGUCHI
23	2											
24		G	MS	80		0MG/KG	78WK	5DY/WK	CATX	----	CTRL	NCI
25		G	MS	100		142MG/KG	78WK	5DY/WK	CATX	LV	CELAEL	NCI
26	2											
27		G	MS	100		282MG/KG	78WK	5DY/WK	CATX	LV	CELFEL	NCI
28		G	RT	80		0MG/KG	78WK	5DY/WK	CATX	----	CTRL	NCI
29	2											
30		G	RT	50		62MG/KG	78WK	5DY/WK	CATX	LV	AEL	NCI
31	2											
32	3											
33		G	RT	50		108MG/KG	78WK	5DY/WK	CATX	LV	AEL	NCI
34		G	RT	50		43MG/KG	78WK	5DY/WK	CATX	LV	AEL	NCI
35	2											
36	3											
37		G	RT	50		76MG/KG	78WK	5DY/WK	CATX	LV	FEL	NCI
38		IP	MS	N		350MG/KG	10DY	N	TX	RP	FEL	SCHMIDT
39	2											
40		0	RT	N		250MG/KG	1DY	1EX	TX	N	FEL	GOHLKE
41		I	HU	5		236PPM	N	N	TX	LV	FEL	HORIGUCHI
42	2											

OBS	YEAR	COMMENTS
21		ENHANCED 24 HR POST-EXPOSURE;
22	1972	INCR. WBC COUNT, TOTAL LV FAT CONTENT, AND
23		PITUITARY ARDENOCORTICOTROPIC HORMONE;
24	1978	TECH. GRADE (90% PURE) IN CORN OIL; B6C3F1, BOTH SEXES;
25	1978	EXP. LEVEL=TWA; POSITIVE CORRELATION—DOSE & HEPATOCEL. CARCINOMA
26		INCIDENCE; TOXIC NEPHROSIS; SLIGHT INCR. IN BODY WT. GAIN PATTERNS (MALES);
27	1978	SAME AS ABOVE; DOSE-RELATED INCR. IN MORTALITY;
28	1978	TECH. GRADE (90% PURE) IN CORN OIL; OBSERVED 32WK;
29		OSBORNE-MENDEL, BOTH SEXES;
30	1978	MALES; EXP. LEVEL=TWA; NO STAT. SIG. INCID. OF NEOPLASTIC LESIONS;
31		RESPIRATORY DISTRESS; BODY WT. RETARDATION; NO ASSOCIATION
32		BETWEEN INCREASED DOSAGE AND MORTALITY;
33	1978	SAME AS ABOVE; 2 CARCINOMAS, 1 NODULE OBSERVED IN THIS GROUP;
34	1978	FEMALES; EXP. LEVEL=TWA; NO SIG. INCIDENCE OF NEOPLASTIC LESIONS;
35		RESPIRATORY DISTRESS; BODY WT. RETARDATION; ASSOCIATION BETWEEN INCREASE DOSE AND MORTALITY;
36		(NOT TUMOR RELATED);
37	1978	SAME AS ABOVE; 20% MORTALITY RATE;
38	1976	AB-JENA & DBA STRAINS; EXPOSED DURING ORGANOGENESIS; EMBRYOTOXIC;
39		LOW INCIDENCE OF SKELETAL MALFORMATIONS; DOSE & PERIOD RELATED EFFECTS;
40	1977	ORAL LD50;
41	1960	CASE REPORTS; OCC. EXP. DEATH FROM ACUTE LV DISEASE;
42		POSSIBLE SYNERGISM WITH 1111PPM TRICHLOROETHYLENE

OBS = Observation or Data Record No., CONT = Continuation Line; NANIMALS = No. of Animals; BODWGHT = Body Weight; EXPLEVEL = Exposure Level; EXPDUR = Exposure Duration; EXPSCH = Exposure Schedule.

Table 3. Definitions of Effect Levels*

NOEL:	No-Observed-Effect Level. That exposure level at which there are no statistically significant increases in frequency or severity of effects between the exposed population and the appropriate control.
NOAEL:	No-Observed-Adverse-Effect Level. That exposure level at which there are no statistically significant increases in frequency or severity of adverse effects between the exposed population and the appropriate control. Effects are produced at this level, but they are not considered to be adverse.
EL:	The exposure level in a study or group of studies which produces statistically significant increases in frequency or intensity of effects between the exposed population and its appropriate control. It has not been decided whether these effects are adverse.
AEL:	Adverse-Effect Level. The exposure level in a study or group of studies which produces statistically significant increases in frequency or severity of adverse effects between the exposed population and the appropriate control.
NOFEL:	No-Observed-Frank-Effect Level. The study was directed toward eliciting frank effects, but none were observed of statistical significance. Other less severe toxic effects may have been present but were not investigated.
FEL:	Frank-Effect Level. That exposure level which produces unmistakable adverse effects or gross toxicity, such as irreversible functional impairment or mortality, at a statistically significant increase in frequency or severity between an exposed population and its appropriate control.
NOCEL:	No-Observed-Cancer-Effect Level. The study was directed toward eliciting carcinogenic response. No such responses of statistical significance were observed at this exposure level. Other toxic effects may have been present but were not investigated.
CEL:	Cancer-Effect Level. Statistically significant cancer responses were observed at this level. Significance could be based on comparison with the control group or on a significant dose-response trend using several dose groups.
CTRL:	Control group. No experimental exposure although a background exposure may exist.

*These designations only note the effects actually observed and reported by the research scientist. Levels where no effects were observed (NOEL, NOAEL, NOFEL, NOCEL) do not ensure safety or freedom from risk and may only reflect the limitations of the study.

Applications of the STARA Data Base

The STARA data base is specifically designed for easy access by statistical routines and mathematical modeling programs. Thus, it is especially suitable for development and testing of risk assessment algorithms and extrapolation models. Because STARA is organized first by chemical, it is also useful for rapid evaluation of a chemical's toxicity. The graphical output in particular provides a ready tool for determining how well an existing standard or criterion is supported by the toxicity data.

Species Extrapolation of Dose. The frequent lack of adequate human data forces the risk assessor to rely on animal studies and use some type of extrapolation from animal to man. The development of standard procedures for dose extrapolation has been dramatically enhanced by the STARA data base. An extrapolation model can be programmed and then automatically applied to hundreds of chemicals with minimal effort, since the programs can access the needed data directly from the computer files. The behavior of the model can then be evaluated regarding its general applicability to any chemical. Other issues that can be similarly tested are the extrapolation from one route of exposure to another, and the influence of aging on toxicity.

Rapid Response Preliminary Health Hazard Assessments. The Rapid Response toxicity assessment project at ECAO-Cin was the first application of the STARA data base. This project provides EPA Regional or Program offices with a preliminary prediction of health hazards attributable to contamination from spills or hazardous waste site releases. These assessments are telephoned to the requestor within two working days of the request and are often followed by a longer written report within two to four weeks. Rapid Response assessments address only toxic potential. No judgments of the safety of a site nor recommendations for a course of action are included in either the preliminary assessment or the follow-up report.

The STARA data base has made projects such as the Rapid Response preliminary site assessments not only possible but practical as well. Before STARA was implemented, site assessments, whether emergency or routine, were performed in a similar and time-consuming fashion—sifting through quantities of literature before finding pertinent information. Response could take as long as several weeks, which is not very useful in emergency cases but was the best effort then available.

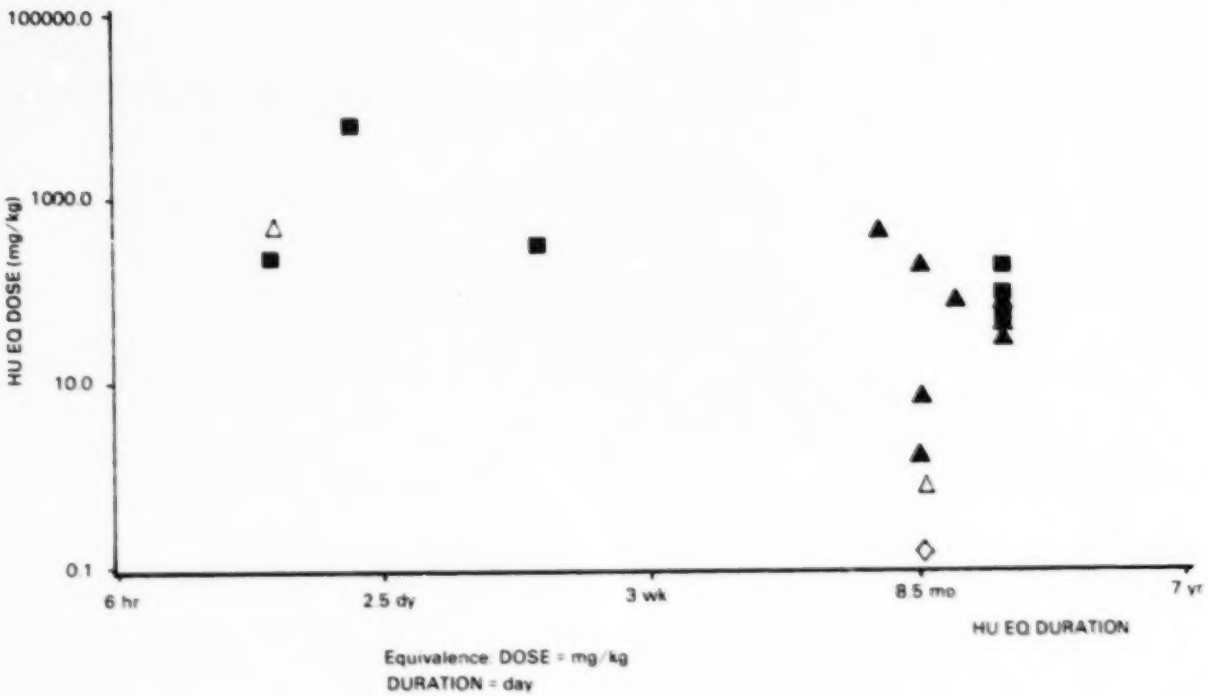
Now, however, specific data can be accessed for any chemical within minutes. Comparisons between chemicals may be made in any number of areas: target organs attacked, type of length of exposure, reactions of different species tested, and so on. Graphs are used to pinpoint studies in relation to dosages, effect levels and other distinctive characteristics. Human equivalent exposures can be calculated in the STARA system and displayed allowing direct comparison between monitored levels and estimated toxic levels. All these features allow the risk assessor to make several quantitative and judgmental comparisons so that the assessment is based on as much information as possible.

Conclusions

A practical solution for condensing large volumes of toxicity data was found through the creation of the STARA data base by the Environmental Criteria and Assessment Office of the USEPA. The data base is designed for quantitative investigations and has features not available in other toxicity data systems. The system was planned in such a way that modifications or expansions may be accomplished without difficulty.

Efforts are now underway to incorporate STARA data into a public access system. The National Library of Medicine and NTIS are two such options being considered.

Figure 1. **Graphical display of all toxicity data for 1,1,2,2-tetrachloroethane. Equivalence: DOSE = mg/kg DURATION = day, see text. For severity categories, see Tables 2 and 3. Symbols: ◇ NOEL, △ NOAEL, ▲ AEL, ■ FEL.**



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